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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,894	07/07/2003	James M. Hagberg	108172-00097	7034

4372 7590 05/01/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
05/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/612,894	HAGBERG ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 21-29* is/are pending in the application.

4a) Of the above claim(s) *21-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,28 and 29* is/are rejected.

7)☒ Claim(s) *28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18, and 21-29 are pending.
Claims 21-27 are withdrawn as detailed in the previous Office Action of 11/15/2006.
Claims 1-18, 28, and 29 are examined on the merits

Please note: The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office Action is in reply to Applicants' correspondence of 08/20/2007.

Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to put this application in condition for allowance. Any rejections or objections not reiterated herein have been withdrawn in light of the amendments to the claims or as discussed in this Office Action. Any new objections or rejections are necessitated by Applicant's amendments.

This Action is **FINAL**.

Withdrawn Claim Objections

The objections to claims 1, 7, and 13, as set forth in the previous Office Action, are **WITHDRAWN** in light of the amendments to the claim.

New Claim Objections

Claim 28 is objected to because of the following informalities: The term "t-PA" is recited in the last line of the claim as a parenthetical expression, i.e.: "(t-PA)" where the term should not be in parentheses. Appropriate correction is required.

Withdrawn Objection to the Specification – New Matter

The objection to the specification over the amendment filed 08/25/2006 is **WITHDRAWN** in light of the amendment to the specification of 02/05/2008.

Withdrawn Claim Rejections - 35 USC § 112 1st¶ - New Matter

The rejection of claims 1-20 under 35 U.S.C. 112, first paragraph, for new matter reciting claims drawn to identification of subjects with particular PAI-1 alleles **and** particular alleles at the t-PA gene locus, as set forth in the previous Office Action, is **WITHDRAWN** in light of the amendments to the claims.

Withdrawn Claim Rejections - 35 USC § 112 1st¶ - New Matter

The rejection of claims 6, 12, and 18, under 35 U.S.C. 112, first paragraph, for new matter is **WITHDRAWN** in light of the amendment to the specification of 02/05/2008.

Claim Rejections - 35 USC § 112 1st ¶ - Written Description

Claims 1-18, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The rejected claims are drawn to methods comprising the steps of identifying 4G allele at the PAI-1 promoter in a human subject and "advising the human subject to engage in exercise training". There is no teaching in the specification as to what is encompassed by or required for any step of 'advising', and the specification as originally filed does not appear to provide for any methods in which any subject is 'advised' to

engage in exercise training for any particular period of time to accomplish some specific result. Furthermore, while the specification teaches a method in which a study population is genotyped, and analyzed before and after some exercise training, the specification as originally filed does not appear to support a method in which some particular subpopulation of the study population (i.e. subjects with at least one 4G allele) is advised to engage in exercise, as seems to be required by the claim.

For these reasons, it is the conclusion that the amendments to the claims are not supported by the specification as originally filed.

Maintained Claim Rejections - 35 USC § 112 1st ¶ - Enablement

This rejection contains new grounds of rejection as necessitated by Applicants' amendments to the claims.

Claims 1-18, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide a method comprising advising a subject to engage in exercise training for a period of time sufficient to decrease the level of t-PA antigen (as required by claims 1-18) or increase the level of t-PA activity (as required by claims 28 and 29).

Nature of the Invention and Breadth of the Claims

The specification asserts that the instant invention relates to identifying genetic markers that correlate with improved success in increasing fibrinolysis levels in subjects

through exercise training (paragraph [0003]) and provides an example in which several surrogate measures of fibrinolysis are provided (i.e.: PAI-1 activity; t-PA activity; and t-PA antigen). The claims are drawn to methods requiring advising a subject to engage in exercise training for a period of time sufficient to decrease the level of t-PA antigen (claims 1-18) or increase the level of t-PA activity (claims 28 and 29), and encompass methods of preventing cardiovascular disease (claims 7-12) and ameliorating cardiovascular disease (claims 13-18 and 29).

The claims encompass subjects with at least one 4G allele (i.e. both homozygous 4G/4G subjects and heterozygous 4G/5G subjects) (claims 1, 4-7, 10-13, 16-20), subjects with heterozygous (i.e. 4G/5G) genotypes (claims 2, 8, and 14), and subjects with homozygous 4G/4G genotypes (claims 3, 9, and 15). The claims encompass exercise regimens comprised of extensive exercise (claims 4, 10, and 16), moderate exercise (claims 5, 11, and 17), and limited exercise (claims 6, 12, and 18).

The nature of the invention requires knowledge of a period of time of exercise training sufficient to decrease the level of t-PA antigen (where any such decreased level of t-PA may prevent or ameliorate cardiovascular disease) or increase t-PA activity.

Direction provided by the specification and working example

The specification teaches an example in which subjects were analyzed for several parameters indicative of fibrinolysis levels (i.e. PAI-1 and t-PA activities and t-PA antigen (paragraph [0031])) prior to participation in an exercise program to establish baseline values, and then after participation in an exercise program (paragraph [0045]).

The specification further teaches the genotyping of the PAI-1 gene promoter with respect to the 4G/5G polymorphic site (paragraph [0042]) by PCR amplification followed by restriction enzyme analysis of the resulting amplicon.

The instant specification provides an analysis of the changes in the measured parameters among the three possible (4G/4G; 4G/5G; 5G/5G) PAI-1 genotypes. The specification indicates that the data provided is an analysis after moderate exercise training for six months (paragraphs [0047], [0048]). The data indicate the following results: the average PAI-1 activity decreased for the 4G/4G and 5G/5G groups, and increased for the 4G/5G group; the average t-PA activity increased for all groups; the average t-PA antigen decreased for all groups. The specification asserts that there is a tendency for subjects with 4G/4G genotypes to respond better than subjects with 4G/5G or 5G/5G genotypes (paragraph [0048]), the analysis of the data (P ANOVA) indicates that none of the changes are statistically significant.

The instant specification does not provide any data concerning any sort of control group, for example a reference group that did not participate in an exercise program.

The specification asserts that improving fibrinolysis prevented the development of cardiovascular disease or alleviated symptoms of cardiovascular disease (paragraph [0007]). There is no indication that either of these two qualities was actually measured in any of the analyzed subjects; Example 1 indicates that subjects were in fact excluded from the study if they had cardiovascular disease.

The specification presents results only from a population of human male and female subjects age 50-70.

The specification presents results only from participation in moderate exercise training (paragraph [0047], Table 1). The specification provides no results from subjects that participated in extensive exercise, or subjects that were involved only in limited exercise.

State of the art, level of skill in the art, and level of unpredictability

The level of skill in the art with regard to identification of PAI-1 gene promoter and t-PA genotypes is high, however the prior art and the instant specification shows that the level of unpredictability in correlating any particular period of time of exercise training sufficient to decrease the level of t-PA antigen or increase t-PA activity is even higher.

Initially it is noted that the while the claims require being able to advise a subject with a 4G PAI-1 promoter allele to engage in exercise training 'for a period of time sufficient to decrease the level of t-PA antigen' or 'for a period of time sufficient to increase the level of t-PA activity', the specification does not give an indication of what such a time period may be for any individual. The analysis of parameters in the Examples provides only measurements at some endpoint that is not clearly identified in the specification, and thus does not provide a teaching of what 'period of time' is sufficient to have the required effects recite in the claims.

The measurements presented in the specification (i.e. Table 1) are 'following moderate exercise training for six months'. This time period is vague considering the definition of terms provided in the specification. According to paragraph [0020], "moderate exercise" means about 5-9 single courses of exercise over an exercise

period that may be from 5 to 50 days, where paragraph [0018] teaches that a "single course of exercise" is any exercise conducted in one day (where the specification provides the non-limiting example that a course of exercise may be from 15 minutes to three hours). It is noted that the data from Table 1 is "following moderate exercise training for six months", where it is not clear from the specification if the "six moths" is considered a moderate exercise period (of e.g. approximately 180 days) or is the result of approximately 4 continuous exercise periods. It appears from these teachings and definitions that the parameters measured in Table 1 as final values may be after exercise training that comprises exercise anywhere from 5 single courses of exercise lasting 15 minutes each over six months to about 180 single courses of exercise each lasting 3 hours over six months.

The extremely wide range of possible requirements for 'moderate exercise', as included in the results of the specification, adds to the unpredictability with regard to being able to advise a subject as to a period of time to exercise to have the required effect. This unpredictability is exemplified by the prior art of Womack et al (2000). Womack shows (Fig 1a) that after acute exercise, t-PA antigen does not remain increased as soon as 30 min post exercise (p.214 - Results in Abstract). Additionally, Cooper et al (2004) shows that both t-PA activity (Fig 1) and t-PA antigen decrease rapidly in the first 10 min after exercise (Fig 2). And while the Examiner recognizes that neither Womack et al nor Cooper et al stratify the results based on PAI-1 polymorphisms, the teachings of both references address the unpredictability of the

requirements of the claims in determining a period of time of exercise for any individual to have the effects required of the claims.

The unpredictability associated with the claimed methods further comes from the fact that the methods require 'advising' a subject to engage in some certain amount of exercise, but do not actually require the subject to perform any particular amount of exercise. It is wholly unpredictable if the mere act of 'advising' a subject to do something will result in the required effects of the claims.

The unpredictability of associating PAI-1 genotype with exercise-induced increases in fibrinolysis is further exemplified by Tiyasangthong (2001). Tiyasangthong examine the hypothesis that exercise training affects fibrinolytic variables (p.103), and that the changes in PAI-1 activity with exercise training is related to PAI-1 polymorphisms (p.107). The reference indicates that there are only significant changes in t-PA activity in heterozygous 4G/5G genotypes, and in t-PA antigen in the homozygous 4G/4G genotypes (Table 7).

Furthermore, claims drawn to methods for preventing cardiovascular disease may be considered as encompassing those methods which completely keep even the most minor forms of cardiovascular disease from occurring; wherein the pertinent method step is engaging a subject in exercise training. And while there may be an inverse relationship between physical activity and the risk of developing cardiovascular disease, the prior art of Sesso et al (2000) indicates that participation in physical exercise is not sufficient to provide a guaranteed prevention of any form or type of cardiovascular disease (Table 2; p.976, right col., lns.44-53). Similarly, while measures

of variables that are associated with the fibrinolytic system (i.e. t-PA activity and t-PA antigen concentration) are provided in the Examples of the specification, there is no indication that even the detected increase in t-PA activity shown in Table 1 is in fact sufficient to in any way ameliorate cardiovascular disease.

Quantity of experimentation required

There would be a large amount of experimentation required to make and use the claimed invention. One would have to conduct a large case-control randomized study to compare t-PA activity and concentration in individuals before any exercise and any point in time after any exercise period to determine what period of time is sufficient to decrease t-PA antigen or increase t-PA activity. Furthermore, one would have to establish that somehow the mere act of advising a subject to perform some particular amount of exercise is sufficient to have the effects required of the claims. There would be further experimentation required to determine if any such exercise in facts prevents cardiovascular disease or ameliorates disease. The fact that measures of t-PA activity and t-PA antigen are not necessarily indicative of those requirements is supported by the conclusions of Womack et al, which teaches, in regards to individuals whose t-PA increased with exercise, "further research is needed to better understand the mechanisms underlying the sustained enhanced fibrinolysis profile, and to determine whether exercise training improves fibrinolysis in this population". Such a study may or may not indicate that there is a reliable and statistically significant exercise dependent increase in prevention of cardiovascular disease, or amelioration of cardiovascular disease, that is associated with a subject's PAI-1 genotype in any particular population.

Conclusion

Taking into consideration the factors outlined above, including the nature of the invention and the breadth of the claims, the state of the art, the level of skill in the art and its high level of unpredictability, the amount of guidance by the applicant and the paucity of working examples, it is the conclusion the an undue amount of experimentation would be required to make and use the invention claimed invention.

Response to Remarks

Applicant has traversed the rejection of claims under 35 USC 112 1st¶ for lack of enablement (pages 9-11 of the Remarks). Applicants' arguments have been fully and carefully considered but are not found to be persuasive.

Applicants' argue (p.9 of Remarks), regarding the data presented in the instant specification demonstrates a significant change in the t-PA activity in 4G/4G subjects and a significant change in t-PA antigen in both 4G/4G and 4G/5G subjects, where Kulaputana et al (2006) provides a statistical analysis of the same data. While the cited article does provide the same data as in the specification, indicating that the changes within the genotypes presented in the specification are significant, this data is not reconciled with the data presented in the cited Tiyasangthong thesis. In the thesis, it is shown that t-PA activity is significantly changed only in 4G/5G subjects, not in 4G/4G subjects, which is different than the results of the instant specification. Further, the thesis does not show a significant change in t-PA antigen in 4G/5G subjects, which is different than the data from the specification. Such differences lend support to the

unpredictability associated with determining a time period of exercise needed for the required effect.

Applicants further argue (p.10 of remarks), that the baseline measurement of exercised subjects taken after screening, dietary stabilization, and prior to commencing exercise is a control as it represents t-PA antigen and activity of subjects consuming diet according to the experimental procedure and who have not exercised. This is not found to be persuasive as there is no indication in the specification that, for example, upon 'dietary stabilization' any subject's t-PA antigen and activity didn't change. For example, if one were to stabilize a subject's diet, then measure t-PA antigen and activity of a diet stabilized subject after 6 months, is it likely that the t-PA antigen and activity would change.

Applicants have further argued (p.10-11 of Remarks) that, which regard to claims requiring preventing or alleviating cardiovascular disease, directly measuring improved fibrinolysis or alleviating symptoms of cardiovascular disease is not necessary because, as the specification recites, there is a link connecting t-PA activity and antigen levels with improved fibrinolysis. Applicants argue that the Examiner must accept statements of fact made by the applicant as true. In the instant case, however, at issue is not whether or not a particular element (i.e. t-PA) is involved in the fibrinolytic system, but whether or not some detected change in that element has a specific result in the complex mulit-system working of the human organism. It is noted that the specification (paragraph [0003]) teaches that t-PA works to create plasmin, which cleaves fibrin. However, somewhat discordant with this teaching, the claims are drawn to methods for

preventing disease and ameliorating cardiovascular disease by decreasing t-PA. Thus the link between t-PA antigen and activity, and the required downstream effects of preventing and ameliorating disease, is not as direct and straightforward as Applicant's argue. The examiner maintains that the instant specification does not provide the required measurement and analysis of disease prevention and amelioration as required by the claims.

For the reasons set forth in the rejection, the rejection is **MAINTAINED**.

New Claim Rejections - 35 USC § 102

It is noted the claims of the instant application, rejected in this section of the Office Action as anticipated by the prior art, have been previously rejected in this Office action under 35 USC 112 1st ¶ as lacking enablement. The prior art cited in this rejection teaches all of the steps of the claimed methods, and meets all of the limitations of the rejected claims. While the cited prior art anticipates an embodiment of the claims, it is does not enable the claims as addressed in the rejection of claims under 35 USC 112 1st ¶. Further it is noted that the specification of the instant application cannot be considered enabling for the methods of the prior art because the instant application does not present the same data, gathered from the same population, as the prior art.

Claims 1-18, 28, and 29 rejected under 35 U.S.C. 102(b) as being anticipated by Väisänen et al (1999) as cited in the IDS.

With regard to independent claims 1, 7, 13, and 28 Väisänen et al teaches methods comprising the steps of determining the genotype of a subject with respect to the 4G/5G PAI-1 gene promoter polymorphism (p.1118, left col., DNA analysis). The methods of Väisänen et al utilize the identification of subjects with 4G/4G, 4G/5G, and

5G/5G genotypes (Table 1), thus identifying subjects with at least one 4G allele as required by claims 1, 7, and 13, and subjects with two 4G alleles as required by claim 28. Further, the reference teaches engaging the subject in an exercise program (p.1118, left col., Cardiorespiratory fitness and exercise intervention), where the subjects of the scientific study are advised to perform a certain training program. With regard to the requirements that the exercise is of a period of time sufficient to decrease t-PA antigen (claims 1-18) or increase t-PA activity, The MPEP in chapter 2100 states:

> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In the examination of the instant application, based on the teachings of the instant specification and the arguments of 02/05/2008 as presented by Applicants, the PTO has basis for believing that the exercise of Väisänen et al meets the limitations of the claims. Further, because the exercise of Väisänen et al is for the required period of time, the exercise prevents cardiovascular disease (claims 7-12) and ameliorates cardiovascular disease (claims 13-18 and 29). Where claims 13-18 and 29 require subject suffering from cardiovascular disease, it is noted that the specification provides no limiting definition or guidance as to what is required for any individual to be 'suffering from cardiovascular disease'. As such, 'cardiovascular disease' is considered to be any amount of fibrin in the cardiovascular system, where the subjects of Väisänen et al would thus meet this interpretation of the term as in a population of individuals as taught

by Väisänen et al at least some of the individuals would have some fibrin in their cardiovascular system.

Regarding claims 2, 3, 8, 9, 14, and 15, Väisänen et al teaches the analysis of subjects that were heterozygous (4G/5G) and homozygous for the 4G allele (4G/4G) at the promoter polymorphic site (p.1118, right col., lns.10-35), and that subjects from both of these groups responded to the exercise intervention (Table 1).

Regarding claims 4-6, 10-12, and 16-18, Väisänen et al teaches the particular nature of the exercise training with regards to duration of the regimen (p.1117, right col., Study design) and courses of exercise (p.1118, left col., Cardiorespiratory fitness and exercise intervention). The reference teaches that the study took place over three years, with exercise occurring three times a week for the first three months, followed by five times a week there after. This meets the definition of extensive exercise as defined in the specification (paragraph [0019]) as the exercise regimen of Väisänen et al includes at least 25 single courses of exercise, and takes place over about 400 days. Relevant to claims 6, 7, 11, 12, 17 and 18, because of the progressive nature of the definitions of limited and moderate exercise as defined in the instant specification (paragraphs [0020]-[0021]), the exercise of Väisänen et al would necessarily be comprised of both limited and moderate exercise.

Conclusion

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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